

REMARKS

This application is amended in a manner to place it in condition for allowance at the time of the next Official Action.

**Status of the Claims**

Claims 1, 8-10 and 13 are amended to correct a misspelling.

Claims 1-4, 6-10 and 13 are pending.

Claims 3, 6-8, and 10 are withdrawn as being drawn to non-elected groups or species.

**Specification Objections**

The Abstract was object to for stating "the invention relates to".

The abstract has been amended in a manner consistent with the kind suggestion in the Official Action, and withdrawal of the objection is respectfully requested.

**Claim Objections**

Claims 1, 2, 4, 9, and 13 were objected to for misspelling "ginkgo".

The claims now correctly spell "ginkgo", and withdrawal of the objection is respectfully requested.

**Claim Rejections-35 USC §103**

Claims 1, 2, 4, 9 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over DI PIERRO WO 02/098436 ("DI PIERRO") in view of THIOLON et al. ("THIOLON"). This rejection is respectfully traversed for the reasons given below.

The position of the Official Action was that it would have been obvious for one of ordinary skill in the art to use the esculoside form THIOLON to treat cellulite, since THIOLON teaches compositions containing esculoside reduce thigh circumference. As to the claimed amounts of esculoside, the position of the Official Action was that it would have been obvious to "determine all operable and optimal concentrations of components because concentration of the claimed esculoside is art-recognized result effective variables because it has a slimming effect, which would have been routinely determined and optimized in the pharmaceutical art.

However, this combination fails to disclose or suggest visnadin, as recited in claim 13, and alternatively in claim 1.

The combination also fails to teach that for which they are offered: the ingredients of claims 1, 2, 4, and 9 would effectively prevent the vascular dysfunctions (e.g., venous insufficiency) and the tissue degeneration that cause cellulite or degenerative panniculopathy.

As discussed in the amendment Filed September 15 2008, DI PIERRO discloses a composition for the treatment of localized

adiposities and cellulite. This treatment utilizes a combination of at least 4 active ingredients:

1. complex of escin/beta-sitosterol with phospholipids,
2. complex of Ginkgo biloba dimeric flavonoids with phospholipids,
3. complex of Centella asiatica triterpenes with phospholipids, and  
one or both of
4. ethylximeninate,
5. standardized Coleus forskolii extract.

There is no suggestion to select only one or two ingredients out of the list and combine the same with other active substances to produce a composition able to prevent cellulite. That is, the claimed invention includes a combination of vascoactive ingredients consisting of a first, second and third component.

THIOLON teaches that the lipolytic effect of slimming liposomes (SLC) is essentially due to caffeine, while esculoside is used for its previously-reported properties (anti-inflammatory properties, ability to stimulate venous resistance and to enhance capillary resistance and quenching of free radicals – see page 210, first paragraph from the top).

In particular THIOLON affirms that “the dramatic increase in the intra-adipocyte cAMP levels observed in the presence of SLC was the result of the caffeine effect and this

surprising  $\alpha$ 2-adrenergic antagonism". (Emphasis added.) Most significantly, THIOLON concludes that "As far as we can know, none of the SLC components was shown to antagonize this receptor" (page 215, last but One paragraph).

This latter sentence is particularly important as it would discourage anyone of ordinary skill in the art to isolate one component, such as esculoside, from the context of the SLC composition, and use it in combination, with other ingredients, since, as stated by THIOLON, none of the SLC components (alone) shows adrenergic antagonism.

Moreover, THIOLON states that the capacity of SLC to dramatically increase cAMP level "should confer to SLC a potent slimming effect", while the other components, including esculoside, are simply expected to produce "well known effects" (page 215, last paragraph to page 216, first par.).

Thus, THIOLON discloses that in order to produce an effective anti-cellulite composition, substances able to induce a potent  $\alpha$ 2-adrenergic antagonism should be used, while substances like esculoside would fail. Accordingly, there would be no reason for one of ordinary skill in the art to select esculoside and combine it with the ingredients known from DI PIERRO.

Furthermore, contrary to the position of the Official Action, the claimed esculoside does not have an art-recognized slimming effect. Rather, as noted above, the esculoside has anti-inflammatory properties, the ability to stimulate venous

resistance and to enhance capillary resistance and quenching of free radicals. Thus, it would have been unobvious to select any particular amount for a slimming effect. A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

With respect to claim 13 in particular, there is no teaching of visnadin in either of these documents.

Therefore, the proposed combination fails to render obvious claims 1, 2, 4, 9 and 13, and withdrawal of the rejection is respectfully requested.

### **Conclusion**

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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**APPENDIX:**

The Appendix includes the following item:

- a new Abstract of the Disclosure